

REMARKS

Claims 1-47 are pending. Claims 15-19 and 21-40 have been withdrawn. All non-withdrawn claims have been rejected.

Claimed Composition

The current application claims a modified oilseed material having specified properties. The application describes processing conditions that are used in forming a modified oilseed material having the claimed properties. The processing conditions needed to form a material having the claimed properties involve a complex combination of parameters including temperature and pH. This can be seen in Tables 10 and 11 of the current application, which report the settings and results of the multivariate experimental design carried out, and from which the parameters may be determined. As discussed below, such conditions are neither described nor inherently present in any of the cited references. Similarly, the materials of the cited references neither demonstrate nor inherently possess the claimed properties.

Claim Rejections - §102

1. Claims 1-14, 41, and 45-47 have been rejected under 35 U.S.C. §102(b) over U.S. Patent No. 4,420,425 ("Lawhon").

Lawhon discusses a method of producing proteins from oilseeds that includes extraction and filtration. The Examiner takes the position that the material of Lawhon would inherently possess the attributes set forth in the pending claims. No indication or arguments have been provided that Lawhon would ever produce a material as claimed, other than an observation that Lawhon uses ultrafiltration and spray drying. However, the claimed material requires more than just being produced using a process including ultrafiltration and spray drying to have the claimed properties.

Inherency requires that the oilseed materials of Lawhon necessarily and unequivocally have all of the properties recited in Applicant's claims. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a

given set of circumstances is not sufficient." *MEHL/Biophile Int'l Corp. v. Milgraum, M.D.*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). This inherency standard is not met by Lawhon.

Attached are two declarations under 37 C.F.R. §1.132 by Michael A. Porter (the "Porter declaration") and Jerome L. Shen (the "Shen declaration"). Both of these individuals have extensive experience in the area of oilseed materials including soy proteins, and processes for producing oilseed materials.

The Porter declaration explains why the properties of the material produced by Lawhon cannot be accurately predicted. One reason for the difficulty of prediction is that Lawhon does not discuss pH control in sufficient detail to understand the pH processing parameters. Furthermore, the pH will likely vary over time in the Lawhon process due to microbial growth. Yet, pH has been found by applicants to have a significant impact on the properties of the resulting material. Another reason for the difficulty of prediction is that Lawhon does not describe the spray drying process except in the most general terms. For example, there is a lack of information regarding the solids content at the spray drying step. As explained in the Porter declaration, the spray drying conditions can also have a large effect on the properties of the resulting material. As described in Items 4, 6, and 7, applicants have found that the properties of produced oilseed materials can vary based on the conditions used, even when using the same equipment and similar feedstock. Item 5 describes some of the additional information that would be required for one of skill in the art to accurately predict the properties of the Lawhon material.

The Shen declaration also explains why the properties of the material produced by Lawhon cannot be accurately predicted. The properties cannot be accurately predicted for reasons including the lack of information concerning the ultrafiltration step of Lawhon. For example, Lawhon fails to describe or provide examples of membranes that might be used, the pressures used during processing, the solids content during processing, and membrane cleaning information. Furthermore, the data that is provided does not appear to always be internally consistent, as described in Item 3e. As explained in Items 3 and 5, the processing of Lawhon is inconsistent and sparse in the reporting of properties and there is insufficient process information to reproduce the method of Lawhon. In addition, several questions arise regarding the process once the data that is provided is examined in greater detail.

In addition, the scarce data that is provided in Lawhon demonstrates the difficulty and wide range of likely properties of the resulting material – even when the method of Lawhon is used to process similar feedstocks by Lawhon himself. These problems are discussed in Item 4 of the Shen declaration, and include the observation that Table 5 in Lawhon shows significant differences in retention data, which likely leads to different material properties.

The data provided in the current application also demonstrates the wide range of properties that modified oilseed materials may possess, even when undergoing similar processing steps. An experimental design, utilizing various processing parameters, was carried out to understand the importance of the various processing factors. As shown in Tables 10 and 11 of the current application, various combinations of the various processing parameters relating to pasteurization temperature and pH, ultrafiltration pH, and solids content led to materials having different properties.

In summary, there is no support for the proposition that Lawhon inherently discloses a material having the claimed properties, merely because the process includes ultrafiltration and spray drying. Lawhon not only lacks the required material data to demonstrate that the material has the claimed properties, but the information provided by Lawhon is insufficient for one of skill in the art to predict the properties of the material of Lawhon. In addition, there is insufficient information for one of skill in the art to accurately reproduce the method of Lawhon with any degree of confidence.

Accordingly, the rejection of claims over Lawhon should be withdrawn.

2. Claim 20 has been rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,630,195 (“Muralidhara”). Once again, the fact that Muralidhara uses ultrafiltration and spray drying is the basis for the rejection.

As described above, in earlier responses, and in the attached declarations, the properties of a modified oilseed material depend upon the various conditions used to process the material. At the time of the filing of Muralidhara (also assigned to Cargill, Inc.), the required interactions between the various processing parameters to produce a high-gel strength material were not understood. There is no indication that the materials of Muralidhara have the claimed properties.

This can be seen in various places in Muralidhara. In one instance, the exemplary processing conditions in Muralidhara differ from those in the current application. For example, in Example 5 of Muralidhara, the conditions include an extraction pH of approx 7.5 to 7.8 with a solids content of approx. 6-7% (col. 22, lines 33-35), and pasteurization conditions of pH 6.8-7.0 with a temperature of 280°F, followed by spray drying. Significantly, the pasteurization temperature is greater than that of any of the experimental design sample pasteurization temperatures. Given the influence of temperature on the properties in the resulting material, as described in the Porter declaration, this provides further evidence that the materials of Muralidhara have properties (including gel strength, dispersion velocity, and ESI) different from those claimed.

In particular, the materials produced in Muralidhara typically have low gel strength. This is described at col. 26, lines 31-42, where the gel strength test results are discussed and analyzed. As stated, the "gel strength of soy isolates is typically low and the four prototypes described in Examples 4-7 are at the low end of the range expected for soy isolates."

Accordingly, the rejection of claims over Muralidhara should be withdrawn.

3. Claims 1-14, 20, 41-42, and 44-47 have been rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,599,556 ("Stark"). Stark is a CIP application of Muralidhara. Once again, the fact that Stark uses ultrafiltration and spray drying is the basis for the rejection.

Even though Stark describes a material having a protein content greater than 85% with 40% of the material having an apparent molecular weight greater than 300 kDa, these gross similarities are insufficient to anticipate the current claims by inherency. In fact, it is the combination of all properties that is novel, and all of the properties are not present in a material merely because some of them are present. In order to illustrate this, shown in the table below are examples of soy isolates, (all having a protein content greater than 90%), and having 40% (or almost 40%) of the material have an apparent MW greater than 300 kDa. Yet none of these meet the required properties of claims 1 (0.5N gel strength), 2(viscosity of at least 0.5), or 3(ESI no more than about 70). This is illustrated by the following instances of materials and properties as reported in Tables 1-8 and 10-11 of the current application:

	MW>300(%)	Gel (N)	ESI	Viscosity
Supro EX 33	42	0.240	83.5	0.412
Samprosoy 90MP	37	0.456	87.0	0.456
EX 10.2	46	0.323	90	0.317
EX 10.3	40	0.412	84	0.371
EX 10.4	42	0.316	78	0.365
EX 10.5	74	0.312	88	0.278

Thus, both commercially available isolates, and isolates produced using ultrafiltration, pasteurization, and spray drying processing steps do not have the claimed properties. Thus, there is no support for the assertion that Stark inherently produces a material having the claimed properties.

Furthermore, Stark also discusses the gel strength of the materials produced. The material produced in Stark "may have a gel strength of no more than 25 g." Referring back to the discussion of gel strength in Muralidhara, we find that these Stark materials also have weak gel strength, at the low end of the protein isolate range.

Accordingly, the rejection of claims over Stark should be withdrawn.

Claim Rejections - §103

4. Claims 42-44 have been rejected under 35 U.S.C. 103(a) over Lawhon alone, or in combination with U.S. Patent No. 6,423,364 ("Altemuller") or U.S. Patent No. 6,841,184 ("Porter").

Altemuller and Porter are cited for their teachings of incorporating soy materials in meats, sauccs, etc.

Altemuller teaches unrefined soy materials that preferably contain less than 65% soy protein on a moisture-free basis (col. 12, lines 38-40). This is also shown, for example, in Table 11 in Column 40. Thus, the material itself does not meet the claimed properties.

Porter, like Stark, is a CIP application of Muralidhara. The discussion relating to the materials and properties of the materials in Muralidhara also apply to Porter. For example, the

gel strength is shown in FIG. 2 or Porter, also illustrating the weak gel strength of the Porter materials.

As neither Altemuller nor Porter make up for the deficiencies discussed above for Lawhon in other respects, the rejection of claims over Lawhon, Altemuller, and Porter, whether taken alone or in combination, should be withdrawn.

5. Claim 43 has been rejected under 35 U.S.C. 103(a) over Stark alone or in combination with Altemuller or Porter.

Altemuller and Porter are cited for their teachings of incorporating soy materials in meat analog applications.

However, as neither Altemuller nor Porter make up for the deficiencies discussed above regarding Stark in other respects, the rejection of claims over Stark, Altemuller, and Porter, whether taken alone or in combination, should be withdrawn.

Double Patenting Rejections

Claims 1-8, 20, 41-47 have been provisionally rejected for nonstatutory obviousness-type double patenting over various claims and combinations of co-pending application 10/432,094 (claims 1-8, 10-16, and 19-43), Altemuller, U.S. Patent 6,841,184 (Porter), and U.S. Patent 6,830,773 (claims 1-21).

As discussed above, none of the references teach or describe materials that meet the requirements of the claims, and thus the pending claims are not merely obvious variations of earlier claims. Therefore, Applicant requests reconsideration and withdrawal of these provisional double-patenting rejections.

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If it would be helpful in advancing prosecution, the Examiner is invited to contact the undersigned at the listed number. This response is being filed together with a Petition for Two-Month Extension of Time, an RCE, and the two discussed Declarations. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,



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